

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA**

MAUREEN PIEKANSKI

Plaintiff,

v.

ALEX AZAR II, in his official capacity
as the Secretary of the Department of
Health and Human Services.

Defendant.

Case No. 3:20-cv-00687-RDM

(Hon. Robert D. Mariani)

Electronically Filed

**MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

Mark W. Fidanza (PA320930)
REED SMITH LLP
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
215-851-8100
mfidanza@reedsmith.com

*Attorneys for Plaintiff
Maureen Piekanski*

Dated: June 12, 2020

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Plaintiff Maureen Piekanski respectfully files this motion for summary judgment on the grounds that collateral estoppel bars the Secretary of the Department of Health and Human Services (“Secretary”) from denying Mrs. Piekanski’s claims for Medicare coverage. Therefore, the coverage denial at issue in this case should be reversed.

I. PRELIMINARY STATEMENT

This is an administrative review case, the resolution of which turns solely on an issue of law. Mrs. Piekanski is suffering from a particularly lethal form of brain cancer known as glioblastoma multiforme (GBM). Even with the proven success of tumor treatment field therapy (TTFT), the two-year survival rate remains well below 50%.

In four other cases, Administrative Law Judges (ALJs) have concluded that TTFT should be covered for Mrs. Piekanski after she repeatedly litigated the issue of whether TTFT is a Medicare covered benefit for her and “medically reasonable and necessary” for her. The Secretary did not appeal those four decisions and they are now final. Nevertheless, the Secretary continues to force Mrs. Piekanski to re-litigate the identical issue during the time she should be spending with family and focusing on her health. This must stop.

II. PROCEDURAL HISTORY OF CASE

As noted above, Medicare ALJs found Mrs. Piekanski’s TTFT to be a Medicare covered benefit for her four times. For one case that was inexplicably denied by ALJ

Glaze on January 18, 2019, Mrs. Piekanski appealed her denied claims at issue here to the Medicare Appeals Council (“Council”).

Consistent with the delays experienced by beneficiaries in the Medicare appeal process, the Council did not rule on Mrs. Piekanski’s appeal within its 90-day adjudicatory timeframe. As a result, Mrs. Piekanski filed an escalation request with the Council. The Council then authorized the filing of a suit, and Mrs. Piekanski subsequently sought judicial review. Mrs. Piekanski’s civil action was initially filed in the United States District Court for the District of Columbia on November 26, 2019 (Dkt. 1). However, upon the Secretary’s objection to that venue (Dkt. 11), the case was transferred to this Court by Order of April 13, 2020 (Dkt. 20). On June 12, 2020, Mrs. Piekanski filed both her First Amended Complaint, and the instant motion for summary judgment.

III. LEGAL BACKGROUND

Collateral estoppel (*i.e.*, “issue preclusion”) is a venerable common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. Under the doctrine of collateral estoppel, “once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation.” *Montana v. United States*, 440 U.S. 147, 153-54 (1979).

Collateral estoppel serves the triple purposes of protecting litigants from the

burden of re-litigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1978).

Collateral estoppel applies if: 1) the issue sought to be precluded is the same as that involved in the prior action; 2) that issue was actually litigated; 3) it was determined by a final and valid judgment; and 4) the determination was essential to the prior judgment. *See, e.g., Anderson v. C.I.R.*, 698 F.3d 160, 164 (3d Cir. 2012). As shown herein, each requirement is satisfied here.

Parallel or concurrent litigation is common. Where there is parallel or concurrent litigation, the case that reaches finality first may have preclusive effect on the other. *See, e.g., Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922); *Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) (“The first to reach final decision can affect the other … through rules of claim and issue preclusion (res judicata and collateral estoppel)’); *Rashid v. Hazleton*, No. 93-1135, 1996 WL 114809, at *4 (E.D. Pa. March 14, 1996) (“the collateral estoppel effect of a judgment is determined by the timing of the judgment, not by the timing of the complaint which led to the judgment’). In other words, a later-filed case that reaches finality first may have preclusive effect on earlier-filed, but still on-going litigation.

Because of the unique posture of the United States as a litigant, the Supreme

Court has held that offensive, non-mutual collateral estoppel does not apply against the United States. *See U.S. v. Mendoza*, 464 U.S. 154, 163-164 (1984) (“The concerns underlying our disapproval of collateral estoppel against the government are for the most part inapplicable where mutuality is present, as in . . . *Moser*.”). As a result, only a party to a prior proceeding with the government can assert collateral estoppel against the government. Indeed, the Supreme Court has affirmed the application of offensive, mutual collateral estoppel against the United States. *See, e.g., U.S. v. Moser*, 266 U.S. 236 (1924). The Third Circuit has discussed the Supreme Court’s affirmation of issue preclusion. *See, e.g., Burlington N. R.R. Co. v. Hyundai N. R.R. Co., Ltd.*, 63 F.3d 1227, 1234 (3d Cir. 1995) (discussing *Moser*, 266 U.S. 236 (1924) - “The government appealed and the Supreme Court affirmed the application of issue preclusion.”).

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, the Supreme Court held:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered

their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

501 U.S. 104, 107-8 (1991) (internal citations omitted); *see also B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S.Ct. 1293, 1302-03 (2015) (confirming that administrative decisions can be a basis for issue preclusion). The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed. App’x. 542 (6th Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ’s work determination); *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015) (DHS collaterally estopped by prior immigration judge’s determination).

That ALJs and the Council review issues *de novo* does not preclude the use of collateral estoppel. Courts routinely apply collateral estoppel in matters subject to *de novo* consideration/review. Indeed, orders granting summary judgment based on collateral estoppel are subject to *de novo* appellate review, as is the application of collateral estoppel itself. *See, e.g., Prusky v. Reliastar Life Ins. Co.*, 532 F.3d 252, 265 (3d Cir. 2008) (applying *de novo* review to both issues).

IV. FACTUAL BACKGROUND

Mrs. Piekanski sets forth the following background information. While it is not

necessary to grant her motion, a discussion of the factual context may assist the Court in consideration of the issues.

A. Tumor Treatment Field Therapy (TTFT)

As noted previously, GBM is an unusually deadly type of brain cancer. Prior to the advent of TTFT, treatment prolonged survival rates to approximately 14-16 months, with only ~5% of patients living after 5 years.

More recently, treatment of GBM using alternating electric fields developed. This is known as tumor treatment field therapy (“TTFT”). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase a progression-free period and overall survival rates. TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it was deemed unethical to withhold TTFT from the control group. Moreover, in the ground-breaking papers published in the Journal of the American Medical Association (JAMA) in 2015 and 2017 that resulted from the clinical trial, TTFT was shown to increase the 2-year survival rate of GBM patients by more than 38% and to nearly triple the five-year survival rate.¹

TTFT, an FDA-approved device worn on the head, was the first significant advance in treating GBM in more than a decade. It has become the standard of care for

¹ See Plaintiff’s Statement of Undisputed Material Facts (“SUMF”), ¶3.

treating GBM and essentially all major private insurers cover TTFT. TTFT extends GBM patients' lives, in some cases, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It has a level one recommendation in the National Comprehensive Cancer Network ("NCCN") guidelines, *i.e.*, there is consensus among the experts, based on a high level of evidence, that TTFT is a recommended intervention.

The sole supplier/manufacturer of the equipment that delivers TTFT is Novocure, Inc. The Optune system is rented from Novocure on a monthly basis. Once a Medicare patient suffering from GBM is prescribed the system, they will have monthly claims for coverage.

B. The Medicare Claims Process

Because GBM requires ongoing treatment, patients treated with TTFT will have multiple claims for Medicare coverage. As in this case, claims are typically submitted every one to three months to reflect a patient's continued use of TTFT.

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process that can (and typically does) take more than a year. At issue in each stage of the process is whether the claim is a Medicare covered benefit/is reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. See 42 C.F.R. §§ 405.920-928. If the claim is denied, the beneficiary can request "redetermination." See 42 C.F.R. §§ 405.960-958. If the claim is still denied,

the beneficiary can request “reconsideration.” *See* 42 C.F.R. §§ 405.960-978.

If the claim is still denied, the Secretary is required to provide “hearings” for appeals to the “same extent” as is provided for in Social Security Hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (citing 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence.

The Secretary has promulgated regulations concerning the conduct of the “hearing” by ALJs. *See* 42 C.F.R. §§ 405.1000-1058. Where the beneficiary is represented by counsel, as in Mrs. Piekanski’s case, the hearings are adversarial. In such a case, the Secretary’s representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a “contractor” to Medicare) has the opportunity to litigate as a party. *See* 42 C.F.R. §§ 405.1008 and 405.1010.

In that capacity, the Secretary (like the beneficiary) can submit evidence (42 C.F.R. § 405.1018); object to the timing of the hearing (42 C.F.R. § 405.1020); object to the issues before the ALJ (42 C.F.R. § 405.1024); present evidence in the form of documents and witnesses (including through subpoenas); cross-examine witnesses, and present an argument (42 C.F.R. § 405.1036); and take discovery (42 C.F.R. § 405.1037). After the hearing, the ALJ issues a written decision that includes findings of fact, conclusions of law, and the reasoning, based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046.

Like the beneficiary, if the Secretary is dissatisfied with the ALJ's decision, the Secretary can appeal to the Council. *See* 42 C.F.R. §§ 405.1100-1140. Regardless of whether the Secretary chooses to participate in the hearing, the Secretary can appeal an ALJ's decision on "own motion" review. *See* 42 C.F.R. § 405.1110. An appeal to the Council (either direct or on "own motion" review) must be made within 60 days of the adverse ALJ decision. *See* 42 C.F.R. § 405.1110(a) and (b)(2).

Finally, if the beneficiary is dissatisfied with a decision from the Council, they can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(g)).

Although the statutes and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2). Thus, Medicare beneficiaries seeking coverage are often thrown into a multi-year effort to obtain coverage or at least get a decision on each denied claim before seeking relief in a federal court.

C. Mrs. Piekanski

Plaintiff Maureen Piekanski is a 65-year-old resident of Throop, wife of over 20 years to husband Theodore, mother/stepmother of four, and grandmother to 10. In 2011, she was diagnosed with GBM, an aggressive malignant brain cancer. Prior to her diagnosis, Mrs. Piekanski was employed at a local grocer's and took a special interest in music and crossword puzzles. She has been living with GBM for nine years, after her physician told her she had 15 months to live upon diagnosis.

After undergoing surgery and chemo-radiation, Mrs. Piekanski was prescribed a TTFT device to treat her GBM.

V. STATEMENT OF RELEVANT MATERIAL FACTS

On four prior occasions, the Secretary rendered a final decision finding TTFT to be a Medicare covered benefit/“medically reasonable and necessary” for Mrs. Piekanski. Inexplicably, one judge determined that TTFT was not a covered benefit for Mrs. Piekanski/not “medically reasonable and necessary”. Mrs. Piekanski was represented by counsel before each ALJ in cases where coverage was granted (SUMF ¶¶5, 23, 32, 41.)

November 7, 2018 Judge Gulin Decision Granting Coverage

On November 7, 2018, ALJ Jeffrey S. Gulin issued a decision favorable to Mrs. Piekanski in ALJ Appeal No. 1-7835229465 for the months September – November 2017. (*Id.* ¶¶6-7.) The issue before Judge Gulin was whether TTFT is a covered benefit for Mrs. Piekanski/is “medically reasonable and necessary” for her. (*Id.* ¶¶10, 12.) Judge Gulin held, among other things, that:

the service is medically reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act. The Appellant is entitled to Medicare coverage for the Elec Stim Cancer Treatment (E0766) provided on the dates of service. . . .

(*Id.* ¶¶11, 13.) The Secretary did not appeal Judge Gulin’s decision. (*Id.* ¶14.)

January 18, 2019 ALJ Glaze Decision Denying Coverage

Inexplicably, on January 18, 2019, ALJ Ryan Glaze issued an inconsistent

decision in ALJ Appeal No. 1-8071086400 denying coverage of Mrs. Piekanski’s TTFT for dates of service December 2017 – February 2018. (*Id.* ¶¶16-17). The issue before Judge Glaze was whether TTFT is a Medicare covered benefit for Mrs. Piekanski. (*Id.* ¶19.) Judge Glaze found that TTFT is not a Medicare covered benefit for Mrs. Piekanski and explicitly held that it is not reasonable and necessary for her. (*Id.* ¶¶20-21 (“... Medicare considers tumor treatment field therapy to not be reasonable and necessary...”)). After the Council failed to issue a ruling within 90 days as required upon her timely appeal, Mrs. Piekanski requested “escalation” pursuant to 42 C.F.R. § 405.1132. (*Id.* ¶50.) Mrs. Piekanski provided therewith three ALJ decisions finding TTFT to be a Medicare covered benefit for her. (*See id.* ¶51.)

September 13, 2019 ALJ Glaze Decision Granting Coverage

Notably, on September 13, 2019, ALJ Ryan Glaze issued a favorable decision for Mrs. Piekanski in ALJ Appeal No. 1-8637781229 for dates of service June – August 2018. (*Id.* ¶¶24-25.) The issue before Judge Glaze was whether TTFT is a Medicare covered benefit for Mrs. Piekanski. (*Id.* ¶28). Judge Glaze held that:

the record before me clearly establishes that the device is medically reasonable and necessary to treat [Mrs. Piekanski’s] condition. . . .

Medicare Part B covers the Optune™ TTFT (E0766) provided to [Mrs. Piekanski]

(*Id.* ¶¶29-30.) The Secretary did not appeal Judge Glaze’s decision. (*Id.* ¶31.)

June 4, 2019 ALJ Soulikias Decision Granting Coverage

On June 4, 2019, ALJ Jenifer Soulikias issued a decision favorable to Mrs. Piekanski in ALJ Appeal No. 1-8415573880 for claims from September – November 2018. (*Id.* ¶¶33-34.) The issue before ALJ Soulikias was whether TTFT is a Medicare covered benefit for Mrs. Piekanski. (*Id.* ¶37). Judge Soulikias held that:

[Mrs. Piekanski] established by a preponderance of the evidence that the electrical stimulation device (code E0766) for TTFT at issue is medically reasonable and necessary and meets the requirements for Medicare coverage.

(*Id.* ¶¶38-39.) The Secretary did not appeal Judge Soulikias’ decision. (*Id.* ¶40.)

January 29, 2020 ALJ Myles Decision Granting Coverage

On January 29, 2020, ALJ James Myles issued a decision favorable to Mrs. Piekanski in ALJ Appeal No. 3-8925380171 for dates of service March – May 2019. (*Id.* ¶¶42-43.) The issue before ALJ Myles was whether TTFT is a Medicare covered benefit for Mrs. Piekanski. (*Id.* ¶46). Judge Myles held, among other things, that:

[b]ased on the evidence, the TTFT devices provided to the beneficiary during the DOS were reasonable and necessary ... and therefore meet the Medicare criteria for coverage. . . .

(*Id.* ¶¶47-48.) The Secretary did not appeal Judge Myles’ decision. (*Id.* ¶49.)

Because the Secretary did not appeal or reopen any of the four favorable ALJ decisions, they have become final. *See* 42 C.F.R. § 405.1048(a)(1)-(2).

VI. ARGUMENT

As a result of the four final decisions finding TTFT to be a Medicare covered

benefit/“medically reasonable and necessary” for Mrs. Piekanski, the Secretary is collaterally estopped from denying that TTFT is a Medicare covered benefit for her. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court should reverse the Secretary’s denial, order coverage, and remand this case with instructions to the Secretary to effectuate the Court’s decision.

A. The Court May Take Judicial Notice of Judge Myles’ Decision

Before turning to the elements of collateral estoppel, addressing an issue that is related to the Record will facilitate the Court’s consideration of this Motion. Notably, 42 U.S.C. § 405(g) (as modified by 42 U.S.C. 1395ff(b)(1)(A)) provides:

The court shall have the power, to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing [the Secretary] with or without the cause for a rehearing.

Mrs. Piekanski believes that this Motion can be granted relying solely on the three favorable decisions in the record. In this case, it is undisputed that these decisions are part of the Record. (*See* SUMF ¶¶6, 24, 33.)

In addition, this Court may properly take judicial notice of the decision by ALJ Myles’ as part of the “pleadings” in this case. For example, in highly similar circumstances, the Seventh Circuit took judicial notice of other proceedings, vacating an agency determination. *Opoka v. INS*, 94 F.3d 392 (7th Cir. 1996). There, the Court was “limited to reviewing the evidence that was before the BIA^[2] at the time it made

² Board of Immigration Appeals.

its decision” in Mr. Opoka’s deportation case. *Id.* at 394. However, after the BIA proceeding concluded, a relevant decision in another proceeding, his wife’s deportation case, issued. *Id.* (“After Mr. Opoka’s proceedings were concluded by the BIA, Mrs. Opoka was granted a suspension of deportation.”). Not only did the Seventh Circuit take judicial notice of the later proceedings to vacate and remand the BIA decision, the Seventh Circuit held it would be “derelict” in its duty if it did not. *Id.* at 394-95.

Just as in *Opoka*, ALJ Myles’ final decision issued after this suit was filed and thus could not have been made part of the record. Relevantly, ALJ Myles found Mrs. Piekanski’s TTFT to be a covered Medicare benefit for her and medically reasonable and necessary for her. As discussed above, this is the same issue present in all the ALJ decisions in the record.

Thus, the Court may properly take judicial notice of Judge Myles’ decision.

B. The Secretary Had a Full and Fair Opportunity to Litigate Decisions Forming the Basis of Collateral Estoppel

In other cases, the Secretary has contended that he did not have a full and fair opportunity to litigate decisions forming the basis for collateral estoppel because of Medicare proceedings below the ALJ level and, irrelevantly, provisions in the Medicare regulations for proceedings with unrepresented beneficiaries.

First, the decisions forming the basis for collateral estoppel here are each those of ALJs and not lower levels of appeal (*e.g.*, reconsideration). Proceedings before the

ALJ (and Council) are those of the Secretary acting in a “judicial capacity” and therefore provide a proper basis for invoking collateral estoppel. *See Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) (“When an administrative agency is acting in a judicial capacity . . .”); *U.S. v. Utah Construction & Mining Co.*, 384 U.S. 394 at 422 (“When an administrative agency is acting in a judicial capacity and resolved . . .”).

Second, Mrs. Piekanski was represented by counsel in the proceedings before Judges Gulin (SUMF ¶5), Soulikias (*id.* ¶32), Glaze (*id.* ¶23) and Myles (*id.* ¶41.). Because Mrs. Piekanski is a represented party, the Secretary’s representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a “contractor” to Medicare) had the opportunity to litigate as a party at the ALJ level. See 42 C.F.R. §§ 405.1008, 405.1010. As noted above, the Secretary could have objected to the timing of the hearing, conducted discovery, called witnesses, submitted briefs, etc. The Secretary did none of those things and chose not to appear at the hearing.

It is fair to apply collateral estoppel against the Secretary when the Secretary had the full array of rights as a litigant, has imposed costs on Mrs. Piekanski, and, having lost, did not appeal, thereby allowing decisions adverse to himself to become final in proceedings in his own Department.

C. Collateral Estoppel Bars the Secretary from Denying Coverage for Mrs. Piekanski’s TTFT Claims

As four final decisions found TTFT to be a covered Medicare benefit for Mrs.

Piekanski and “medically reasonable and necessary” for her, the Secretary is collaterally estopped from relitigating the same issue of TTFT coverage for Mrs. Piekanski.

1. The Issue Sought to Be Precluded is the Same as That Involved in the Prior Actions

In the Medicare program, devices and services that are not “medically reasonable and necessary” are excluded from coverage. 42 U.S.C. § 1395y(a)(1)(A). Thus, whenever a coverage decision has finally determined that a device/service is a Medicare covered benefit, it has necessarily determined that the device/service is medically reasonable and necessary for that particular beneficiary.

In the present case, Mrs. Piekanski seeks to preclude the Secretary from denying that TTFT is a Medicare covered benefit for her (and the sub-issue of whether TTFT is “medically reasonable and necessary” for her).

As noted above, in four final decisions on separate claims brought by Mrs. Piekanski, the ALJ decided the exact same issue of whether TTFT was a Medicare covered benefit for Mrs. Piekanski (and the sub-issue of whether it is “medically reasonable and necessary” for her). For instance, the issue before Judge Gulin in 1-7835229465 was “[w]hether the Elec Stim Cancer Treatment (E0766) provided to the Beneficiary...meet Medicare coverage criteria...[and] [w]hether the services provided are medically necessary...” (sic). (See SUMF ¶¶10, 12.) Judge Gulin then determined that TTFT was a covered Medicare benefit/“medically reasonable and

necessary” for Mrs. Piekanski. (*Id.* ¶¶11, 13.) This very issue was disputed in Judge Gulin’s, Judge Soulikias’, Judge Glaze’s, and Judge Myles’ decisions granting coverage and litigated again in Judge Glaze’s inconsistent January 2019 decision denying coverage.

Specifically, in the denial here, the same issue was presented and decided in the exactly opposite way. *See* January 18, 2019 Glaze Decision issue (“whether payment may be made for the...tumor treatment field therapy (E0766) provided to the Beneficiary”) (*Id.* ¶19); (*id.* ¶20 (“Medicare does not cover the tumor treatment field therapy (E0766) at issue”)); (*id.* ¶21 (“... Medicare considers tumor treatment field therapy to not be reasonable and necessary ...”)).

To the extent the Secretary contends that the issues are different because each decision covers different months, there is no merit to that. As the Supreme Court noted in *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008), issue preclusion bars successive litigation “even if the issue recurs in the context of a different claim.” Thus, the fact that one decision concerns November 2018 (granting coverage) while another concerns February 2018 (denying coverage) is of no moment because there is no evidence that the month is material to the conclusions that TTFT was medically reasonable and necessary and a coverage benefit for Mrs. Piekanski.

Indeed, collateral estoppel’s purpose in avoiding inconsistent results (*Allen*, 449

U.S. at 94; *Parklane*, 439 U.S. at 326) is illustrated here:³

September – November 2017	Covered (ALJ Gulin)	Newly Diagnosed
December 2017 – February 2018	Not Covered (ALJ Glaze)	Recurrent
June – August 2018	Covered (ALJ Glaze)	Newly Diagnosed
September – November 2018	Covered (ALJ Soulakias)	Recurrent
March – May 2019	Covered (ALJ Myles)	Recurrent

How Mrs. Piekanski could go from “newly diagnosed” to “recurrent”, then back, then back again (with conflicting decisions issued by the same judge) is unexplained. Avoiding these non-sensical results is one purpose of collateral estoppel.

Thus, in all TTFT claims brought by Mrs. Piekanski, the same determinative issue was presented and decided.

2. The Issue was Actually Litigated in the Prior Proceedings

As noted by the Third Circuit: “An issue is ‘actually litigated’ when it is ‘properly raised, by the pleadings or otherwise, and is submitted for determination, and is determined.’” *See O’Leary v. Liberty Mutual Ins. Co.*, 923 F.2d 1052, 1066 (3d Cir. 1991) (citing RESTATEMENT (SECOND) OF JUDGMENTS § 27 cmt. d (1982)).

Here, Mrs. Piekanski sought Medicare coverage for her TTFT in each of the

³ See SUMF ¶52.

four favorable cases. (*See, e.g.*, SUMF ¶8 (Judge Gulin) (“Mrs. Piekanski seeks coverage for Elec Stim Cancer Treatment...”); *id.* ¶35 (Judge Soulikias) (“Beneficiary is challenging the denial of coverage for an electrical stimulation device...”)). Mrs. Piekanski properly raised the issue of Medicare coverage of TTFT for herself by appealing the negative QIC decisions. (*See, e.g.*, *id.* ¶9 (Judge Gulin), *id.* ¶36 (Judge Soulikias)).

Further, each ALJ actually determined that issue in rendering their favorable decisions. (See Sec. V above.) Thus, the issue of Medicare coverage for Mrs. Piekanski’s TTFT/whether it is “medically reasonable and necessary” for her was actually litigated before each ALJ.

3. The Issue was Determined by a Valid and Final Judgment

Of course, the four favorable ALJ decisions being invoked for collateral estoppel are final decisions by ALJs within the jurisdiction of the Secretary’s Department. Thus, the validity of the judgments is beyond dispute. “A judgment is ‘valid’ when it has been rendered by a court of competent subject matter jurisdiction and the party against whom judgment is rendered either has submitted to the jurisdiction of the court or has been afforded adequate notice.” *See O’Leary*, 923 F.2d 1052, 1066 (3d Cir. 1991).

Likewise, that the Secretary did not appeal the four adverse judgments and the fact that they have become final is also beyond dispute. *See* 70 Fed. Reg. 36386-7

(June 23, 2005) (“The ALJs within the Office of Medicare Hearings and Appeals issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council[.]”); 42 C.F.R. § 405.1100(c) (“The Council issues a final decision . . .”); *see also Smith v. Berryhill*, 139 S.Ct. 1765, 1775-6 (2019) (under APA, action is “final” if it: 1) marks the consummation of the agency’s decision making process; and 2) is one by which rights have been determined or from which legal consequences will flow). Thus, the third factor for collateral estoppel is established for Mrs. Piekanski.

4. The Determination was Essential to the Prior Judgment

As detailed above, the issue being litigated in each of the four favorable determinations was whether TTFT is a Medicare covered benefit for Mrs. Piekanski/is “medically reasonable and necessary” for her. Given that it is the determinative issue, the decision on it in each case is an essential part of each decision. Further, as detailed above, essential to the prior, final judgments was a determination that TTFT was “medically reasonable and necessary.” Because something is a Medicare covered benefit only if it is “medically reasonable and necessary”, that determination was critical to each judge’s decision. Each judge explicitly decided the sub-issue of medical reasonableness and necessity. (SUMF ¶¶13, 30, 39, 48.)

The fact that, in some cases, a favorable ALJ decision giving rise to collateral estoppel occurred after the unfavorable ALJ decision at issue here is of no moment. As indicated, whichever decision reaches finality first may give rise to collateral

estoppel against earlier, but still on-going, litigation. *See, e.g., Rashid v. Hazleton*, 1996 WL 114809 at *4 (E.D. Pa. March 14, 1996). Once the Secretary elected to allow the four favorable decisions for Ms. Piekanski to become final, he should be estopped from continuing to litigate that same issue in all pending claims by the same Plaintiff.

D. The Decision at Issue Should be Reversed and Coverage Ordered

In applying collateral estoppel against the Secretary with respect to the issue of whether TTFT is a Medicare covered benefit for Mrs. Piekanski/“medically reasonable and necessary” for her, the decision at issue should be reversed. ALJ Glaze’s denial is premised solely on the conclusion that TTFT is not a Medicare covered benefit/not “medically reasonable and necessary.” That is, there is no other basis for the denial of coverage (*e.g.*, the beneficiary passed away). Thus, if the Secretary is collaterally estopped from re-litigating that issue, there is no reason coverage should be denied.

VII. CONCLUSION

For the reasons set forth above, the Secretary should be collaterally estopped from denying that TTFT is a Medicare covered benefit for Mrs. Piekanski and medically reasonable and necessary for her. Mrs. Piekanski respectfully asks this Court to enter an Order granting her Motion for Summary Judgment and, pursuant to 42 U.S.C. § 405(g) (fourth sentence), remand this matter to the Secretary with

instruction to cover Mrs. Piekanski's claims.

Respectfully submitted,

/s/ Mark W. Fidanza
REED SMITH LLP
Mark W. Fidanza (PA320930)
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
(215) 851-8264
MFidanza@reedsmith.com

Attorney for Plaintiff
Maureen Piekanski

Dated: June 12, 2020

CERTIFICATION BY COUNSEL PURSUANT TO LOCAL RULE 7.8(b)(2)

I, Mark W. Fidanza, hereby certify that although this Brief exceeds fifteen (15) pages, the word count contained in this brief is 4,994 words, exclusive of the Cover, Table of Contents, Table of Authorities, Signature Block, and Certificate of Service. Thus, this Brief complies with the word-count limitation set forth in Local Rule 7.8(b)(2).

Dated: June 12, 2020

/s/ Mark W. Fidanza

Mark W. Fidanza

CERTIFICATE OF SERVICE

I, Mark W. Fidanza, certify that a true and correct copy of the foregoing Memorandum of Law in Support of Plaintiff's Motion for Summary Judgment was filed electronically on June 12, 2020, is available for viewing and downloading from the federal court's ECF/CM system, and will be automatically served upon registered counsel of record by ECF/CM.

/s/ Mark W. Fidanza

Mark W. Fidanza